Frequently Asked Questions

General Information: Mifegymiso

Q: When was the mifepristone (RU-486)/misoprostol drug regimen first approved in Canada? In other countries?
A: Mifegymiso was approved by Health Canada in July 2015 (1). It was first approved in France and China in 1988, and is now approved for use in over 60 countries (2).

Q: How does Mifegymiso, a combination of mifepristone and misoprostol, induce abortion?
A: Mifepristone is a potent progesterone receptor antagonist that causes the endometrium to be unable to support a growing embryo. Because progesterone is unable to exert its effects, the uterine lining breaks down, and bleeding begins. Mifepristone also increases prostaglandin levels that cause the cervix to dilate and the smooth muscle fibres in the myometrium to contract, facilitating abortion and evacuation of intrauterine contents (3).

Pre-Procedure Care

Q: What topics should I cover in the initial pregnancy options counselling session with a women presenting for an abortion?
A: These sessions typically include a discussion of: (a) pregnancy options (abortion, term pregnancy, adoption); (b) abortion methods; (c) risks and benefits of each abortion method; (d) confirmation that the decision is voluntary and that support is present; (e) emotional needs, coping abilities and values; (f) contraceptive options (4).

Q: How do I determine if the woman who consults me is eligible for medical abortion using the mifepristone/misoprostol (MIFE200/MISO800) regimen?
A: The woman must meet the following requirements as per Health Canada regulations (5):

- 15 years of age, or older.
- Intra-uterine pregnancy with a gestational age up to 49 days LMP as confirmed by ultrasound.
- Patient does not have the conditions in which Mifegymiso use is contraindicated (listed under Medical Abortions Regimen).
- Patient has been counselled on the risks and benefits of Mifegymiso, and has provided written informed consent.

You may also use an evidence-based medical abortion protocol given that the woman has no contraindications, she is counselled on the risks and benefits of the medical abortion protocol, has provided written informed consent ant that she is aware this is an evidence-based medical abortion protocol.

Q: Do I need to order or perform an ultrasound before providing a medical abortion?
A: According to the Canadian monograph for MIFE/MISO, "an ultrasound shall be performed before medical abortion" (6). Ultrasound is the criterion standard for confirming that pregnancy location and gestational age (7,8) fall within the guidelines for MIFE/MISO use. This is especially important when there is a risk of ectopic pregnancy or when the woman is unsure of her LMP date. However, if a woman is sure of her LMP, her gynecological examination correlates to LMP and she presents no signs or symptoms of ectopic pregnancy, evidence based guidelines indicate an ultrasound may not be required and the need for one should not delay abortion at early gestation (4). When ultrasound is not performed, a baseline βhCG should be drawn.

Q: How do I provide a medical abortion in the setting of a pregnancy of unknown location (ie. ultrasound and βhCG are not diagnostic of an intrauterine pregnancy)?
A: A safe approach to take before medical abortion to rule out ectopic pregnancy is listed in the table below (9–13):

Scenario	Recommendations
(1) risk factors or signs/ symptoms of ectopic pregnancy are present **(2)** no intrauterine gestational sac present	Regardless of the βhCG, further investigation to eliminate ectopic pregnancy is required.
(1) serum βhCG level > 2000 IU/L (2) no intrauterine gestational sac present	Regardless of the risk factors and symptoms, further investigation to eliminate ectopic pregnancy is required.
(1) no risk factors or signs/symptoms of ectopic pregnancy are present (2) no gestational sac **(3)** βhCG ≤ 2000 IU/L	Proceed with medical abortion, but inform the woman about the risks and symptoms of ectopic pregnancy requiring emergency care. Follow-up serum βhCG levels required on day 3 and 7 after mifepristone.
(1) no risk factors or signs/symptoms of ectopic pregnancy are present (2) likely gestational sac is present without a yolk sac or fetal pole	Proceed with medical abortion, but inform the woman about the risks and symptoms of ectopic pregnancy requiring emergency care. Follow-up serum βhCG levels required on day 3 and 7 after mifepristone.

Medical Abortion Regimens

Q: What is the approved MIFE200/MISO800 dosing regimen in Canada?
A: 200 mg mifepristone, oral, followed by 800 µg of misoprostol, buccal, 24-48 hours after the dose of mifepristone (5). Alternate evidence-based routes of administration of misoprostol include sublingual and vaginal (4).

Q: Up to how many days gestation is the MIFE200/MISO800 regimen considered effective?
A: Use of the MIFE/MISO regimen is indicated up to 49 days gestation (6). Evidence-based off-label use of this regimen is considered effective up to 70 days gestation (14–17). The effectiveness of various MIFE200/MISO800 regimens is reproduced below from the Medical Abortion SOGC guideline (4):

Medication and dose	Gestational age	Effectiveness
Mifepristone 200 mg oral/ misoprostol 800 µg buccal or vaginal	≤ 49 days	95.5% - 97% (18–22)
Mifepristone 200 mg oral/ misoprostol 800 µg buccal, vaginal or sublingual	≤ 63 days	94.2% - 99.8% (18–27)
Mifepristone 200 mg oral/ misoprostol 800 µg buccal	64-70 days	90%-95.9% (16,17)

Q: What are absolute contraindications to using MIFE200/MISO800?
A: There exist several conditions in which MIFE200/MISO800 is contraindicated (6). These include:
(1) Ectopic pregnancy (28)
(2) Chronic adrenal failure (MIFE is a potent anti-glucocorticoid) (28)

(3) Inherited porphyria (29)
(4) Uncontrolled asthma (30)
(5) Known hypersensitivity to product ingredients (31)
(6) Ambivalent about the decision to abort

Q: What are relative contraindications to using MIFE200/MISO800?
A: Relative contraindications for the use of MIFE200/MISO800 include:
(1) Unconfirmed gestational age (32)
(2) IUD in place (ectopic pregnancy must be ruled out (28); device should be removed prior to medical abortion)
(3) Concurrent long-term systemic corticosteroid therapy (30)
(4) Haemorrhagic disorders or the use of anti-coagulation therapy (28)

Q: If the woman who consults me for a medical abortion has an absolute contraindication to using MIFE200/MISO800, what are her options for abortion?
A: For pregnancies up to 63 days, you can offer her a medical abortion using 50 mg oral/intramuscular methotrexate followed by 800 μg vaginal/buccal misoprostol 3-5 days later (33). The use of misoprostol only regimens can also be used for pregnancies up to 63 days, although this is less effective then other regimens (34–36). You can also offer her the choice of a surgical abortion under sedation-analgesia,

Q: What are the serious risks for a woman posed by medical abortion?
A: The risk of mortality associated with medical abortion is about 0.4 in 100,000 which is similar to that of surgical abortion.(37) The risk of blood transfusion after MA is 0.1% (26). The risk of infection after MA is low (0.016 – 0.019%) (37), but there have been rare reports of fatal infections caused by *Clostridium* and subsequent toxic shock following medical abortion using mifepristone (38–40). However, toxic shock has also been reported following vaginal delivery, spontaneous miscarriage, Caesarean section and other surgical procedures. (34)

Q: What initial clinical and laboratory investigations should I perform for a woman undergoing a medical abortion using MIFE200/MISO800?
A: Baseline vital signs and pelvic examination as directed by history. Lab investigations should include baseline haemoglobin, Rh status, STI screening (for chlamydia, gonorrhoea), other tests if needed (4).

Q: What is the procedure for completing a medical abortion using MIFE200/MISO800?
A: The protocol for proper administration is described below (4):

Day 1: Mifepristone
- Obtain informed consent and prescribe MIFE200/MISO800.
- The woman takes one mifepristone 200 mg tablet orally and swallows with water.
- The woman takes home four misoprostol tablets (200 μg each).

Day 2-3: Misoprostol
- 24-48 hours after taking mifepristone, women places four misoprostol tablets (800 μg) between the cheeks and teeth and leaves them in place for 30 minutes; she then swallows any leftover fragments with water.
- Alternative routes of misoprostol administration include sublingual (under the tongue for 20 minutes then swallow with water) or vaginal (place high in vagina and lie down for 30-60 minutes).

Day 7-14: Follow-up
- Verify that abortion has been completed using ultrasound and/or serial βhCG measurements.

Q: What will a woman experience during her medical abortion with mifepristone?

A: A few hours after misoprostol administration, the woman should expect bleeding heavier than a regular period with clots for 2-4 hours. If the pregnancy is less than 56 days gestation, they may pass tissue but not an obvious fetus. Cramping and pain will occur before and at the time of expulsion (4). Misoprostol can cause diarrhea, chills and fever, nausea, vomiting, headache and dizziness (18,24,33,41,42).

Q: What factors influence the pain experienced by the woman during her medical abortion?
A: Women under 18 more frequently report pain as compared to adults when using MIFE200/MISO800 (5). Higher doses of misoprostol and older gestational age are also associated with more pain (43). Less pain is reported by women with previous deliveries (43).

Q: How long does a medical abortion using mifepristone take to complete? Using methotrexate?
A: The mean number of days to completion as reported in a Canadian RCT (n = 1,042) was 3.3 days using mifepristone and 7.1 days using methotrexate (33).

Q: How can I define "too much bleeding" to a woman undergoing a medical abortion?
A: If, after her abortion, for more than 2 consecutive hours the woman is soaking 2 maxi pads per hour and/or if she is experiencing dizziness, light-headedness or a racing heart rate, this is **"**too much bleeding**"** (4). You should provide women with access to emergency medical care directly or via telephone (44).

Q: What symptom management can I offer to the woman who is undergoing a MIFE200/MISO800 medical abortion?
A: NSAIDs for pain control can be used in most instances, such as ibuprofen 200-400 mg every 8 hours or naproxen 225-500 mg every 12 hours on an as-needed basis (4). A mild opioid analgesic (eg. codeine or oxycodone) prescription can also be offered as need to treat significant cramping or severe pain (43). Dimenhydrinate, ondansetron, or diclectin can be offered to manage nausea.

Post-Abortion Care

Q: What can I do to determine if the woman's medical abortion has been completed?
A: Ultrasound and/or serial βhCG measurements can be used to definitively confirm pregnancy termination. A drop of serum βhCG levels of 80% or more from pre-treatment to 7-14 days later is evidence of a successful medical abortion. Clinical history alone cannot identify medical abortion failure (45,46). A structured symptom checklist together with a urine semi-quantitative pregnancy test can be effective at diagnosing ongoing pregnancies (45,47).

Q: What are some potential complications of a MIFE200/MISO800 medical abortion regimen that patient woman may experience?
A: Retained products of conception that requires aspiration occurs in, on average, 3-5% of women (26,48). In a retrospective study of 13,713 women, ongoing pregnancy occurred in 2.1% of women at 57-63 days LMP, and in 3.1% of women at 64-70 days LMP (15). Post-abortion infection, in a 2004 systemic review, was found to occur in 1.33% for mifepristone and vaginal misoprostol and 0.18% for oral misoprostol (49). Endometritis and undefined genital tract infection were the most common infection types (49).

Q: What should I tell women so that they can recognize the signs and symptoms of complications?
A: Retained products of conception may cause heavy or prolonged bleeding and cramping, or a failure of the expected bleeding (if no expulsion has occurred). A woman with an ongoing pregnancy will have continuing pregnancy symptoms and will likely have had minimal or no bleeding following misoprostol administration (50). The usual signs and symptoms of pelvic infections include abdominal or pelvic pain, foul-smelling discharge, prolonged bleeding or spotting, fever or chills, tenderness and an elevated white blood cell count (34,44,51,52).

Q: What symptoms should prompt a woman who has undergone a medical abortion to seek medical attention?

A: If she is experiencing (44):

- Prolonged or heavy bleeding (soaking more than 2 pads per hour for 2 consecutive hours);
- Fever that has lasted more than 24 hours
- Feeling generally unwell for more than 24 hours following misoprostol administration

Q: How often does treatment failure using MIFE200/MISO800 occur?
A: Treatment failure (defined as viable pregnancy, non-viable persistent pregnancy, and persistent bleeding and abdominal pain that required a surgical termination of pregnancy) occurred in 2-4.8% of women undergoing medical abortion with mifepristone/misoprostol up to 49 days of gestation as indicated in analysis of the three pivotal clinical trials considered by Health Canada (1).

Q: How can I tell if my patient is experiencing toxic shock due to a clostridial infection?
A: The woman will present with vague symptoms including general malaise with nausea, vomiting, and diarrhea, weakness, absence of fever (or mild fever), minimal abdominal pain, flu-like symptoms, hypotension, tachycardia, edema, high hemoglobin level (hemoconcentration) and a high white blood cell count (34,40,51,53,54).

Q: What can I offer to a woman if she has an ongoing pregnancy following a medical abortion?
A: At the first follow-up, offer a second dose of misoprostol 800 μg or surgical evacuation. If cardiac activity is present 7 days after the second dose of misoprostol, then surgical evacuation should be offered.

Q: What should I counsel to a woman regarding contraception use following a medical abortion?
A: You should inform the woman that ovulation can occur as quickly as 8 days (mean 20.6, with a range of 8-36 days) after starting the medical abortion procedure (55). Hormonal contraception method should be started immediately after taking misoprostol (56,57). Condoms and spermicide should be used as soon as intercourse resumes (58). If a woman requires an IUD insertion, it should be inserted at the follow-up visit, after a successful abortion has been confirmed (59–61).

Q: Does medical abortion affect the woman's fertility or future pregnancy outcomes?
A: No. Fertility is rapidly restored after a medical abortion. Women who have undergone MA have no increased risk of preterm delivery or low birth weight or low mean length compared with women that have not had a previous abortion (62).

Q: How can I support the woman emotionally after her abortion?
A: The emotional response to abortion can vary widely among women. However, all women will benefit from the provision of a disclosure-friendly and nonjudgmental environment, normalizing common reactions and exploring supports and coping strategies. If you identify women who are not coping well, facilitating referrals for further counseling is required (63–71).

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